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REMARKS

The Applicants request reconsideration of the rejection.

Claims 1, 4, and 6-9 are now pending.

Claims 1, 4, 6-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenchein et al., U.S. 6,113,558 (Rosenchein) in view of Ueberle et al., U.S. 4,819,621 (Ueberle). The Applicants traverse as follows.

Each of the independent Claims 1, 4 and 9 has been amended to limit the sound detector to detect an audible sound having a frequency from 250 to 550 Hz, during exposure of therapeutic ultrasound, the audible sound being generated in the region to be coagulated. The Applicants refer the Examiner to the specification at Page 19, lines 22-26 for an example of support.

As now limited, the inventive therapeutic ultrasound system has a sound detector that accurately detects sound components caused when bubbles generated in the affected area are expanded to burst, or when the bubbles destroy tissue. See Page 18, lines 9-14 and Page 19, line 19 through Page 20, line 11 for example. Based on this detection, in performing irradiation of therapeutic ultrasound a plurality of times,

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the continuous insonation time from bubble generation is always appropriately set even if the period of time taken for each bubble generation differs from those for other generations, thereby making it possible to secure the coagulation effect for each irradiation and to suppress the emergence of side effects due to overheating. See Page 8, line 17 through Page 9, line 4 for example.

More particularly, each of the independent claims requires an ultrasonic transducer which irradiates a therapeutic ultrasound having a frequency from 1 Mhz to 10 Mhz on a region to be coagulated by heat of the therapeutic ultrasound, and a sound detector which detects, during exposure of the therapeutic ultrasound, an audible sound generated in the region to be coagulated, the audible sound having a frequency from 250 to 550 Hz. Claim 1 further requires a "unit" which detects a point of time of detection of the audible sound using a cross-correlation function between a waveform of the detected audible sound and a typical waveform of an audible sound previously obtained, during irradiation of the therapeutic ultrasound, in the region to be coagulated, wherein the unit sends a signal expressing

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detection of the audible sound to a control unit which controls irradiation of the therapeutic ultrasound. Claim 8 recites a "unit" which detects a point of time of detection of the audible sound by comparing an FFT spectrum before the start of irradiation of the therapeutic ultrasound with the FFT spectrum after the start of irradiation of the therapeutic ultrasound. Claim 9 recites a "unit" which detects a point of time of detection of the audible sound using a cross-correlation function between the FFT spectrum of the detected audible sound and a typical FFT spectrum of a typical waveform of an audible sound previously obtained, during irradiation of the therapeutic ultrasound, in the region to be coagulated, wherein the unit sends a signal expressing detection of the audible sound to a control unit which controls irradiation of the therapeutic ultrasound.

On the other hand, the primary reference to Rosenschein discloses that, by placing a microphone on the outside of a subject receiving ultrasound treatments, there is obtained feedback regarding whether cavitation is occurring. In other words, Rosenschein uses a microphone to detect the development of cavitation, which is said to be linearly related to the

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output intensity of the microphone (Column 8, lines 1-2).

Rosenschein recognizes no relevance of the frequency range of any audible sound generated as a result of the cavitation.

Ueberle discloses a method for detection of cavitation during medical application of high sonic energy by generating a reception signal from an initial reflection of a test signal, and then examining the reception signal by comparison with the test signal to detect the presence of an impedance jump. In Column 3, lines 1-7, Ueberle teaches that it is possible to encompass and evaluate an enlarged zone by scanning a longer period of the reception signal and seeking a signal which corresponds to a signal occurring in the case of an attenuated echo, in a computer by establishing a cross-correlative function between the actual reception signal and a reference signal. Ueberle, however, does not disclose or suggest the feature of detecting audible sound from 250 to 550 Hz, the audible sound being generated in a region to be coagulated by irradiating the region with therapeutic ultrasound, detecting a point of time of detection of the audible sound, and irradiating the therapeutic ultrasound from the point of time of detection of the audible sound until

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expiration of a continuous insonation time of the therapeutic ultrasound. Thus, even in combination with Rosenschein, Ueberle does not teach the claimed invention.

The difference between merely detecting the development of cavitation (as taught by Rosenschein) and the detection of audible sound within the claimed frequency range of 250 to 550 Hz is not an obvious one. The combination of Rosenschein and Ueberle does not provide or even suggest the effect that the audible sound caused when the bubbles generated in the affected area are expanded to burst or when the bubbles destroy the tissue, can be accurately detected. Indeed, as noted in the excerpt from Ultrasound: Medical Applications Biological Effects, and Hazards Potential, submitted with the Reply filed April 12, 2005, acoustic emission detected from water and living tissue during ultrasound exposure at a frequency of 2.7 Mhz results in cavitation occurring in the water or living tissue having a strong signal at the fundamental (2.7 Mhz) and the half-harmonic, but weaker signals at the second, third, and higher harmonics. Especially when cavitation occurred in living tissue, a wider bandwidth was centered at a frequency below the half-harmonic

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spike. This bandwidth emission was seen in the range of about 500 kHz to 1.5 Mhz. No substantial emission was detected below 500 kHz.

In the case of Rosenschein, if therapeutic ultrasound having a frequency of 20 kHz (Column 5, lines 28-41) were applied to induce cavitation, it seems that an acoustic emission of 20 kHz as a fundamental and 10 Hz as a half-harmonic would be strongly detected during insonation, according to Ultrasound. However, one would expect no strong emission to be detected below 1 kHz in the case of Rosenschein, according to Ultrasound.

Therefore, the now-claimed audible sound detection range of 250 to 550 Hz from coagulated tissue is based on a different phenomenon from Rosenschein, whether taken individually or in any motivated combination with Ueberle, and does not represent an obvious modification from such a combination. Accordingly, the Applicants respectfully submit that the amended claims are patentably distinguishable from the prior art of record.

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In view of the foregoing remarks and amendments, the Applicants request reconsideration of the rejection and allowance of the claims.

Respectfully submitted,



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